4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 118

[Docket No. FDA-2011-D-0398]

Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance entitled "Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation." The guidance contains questions we have received on the final rule since its publication and responses to those questions, and is intended to assist egg producers and other persons who are covered by the final rule.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Nancy Bufano,

Center for Food Safety and Applied Nutrition (HFS-316),

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5100 Paint Branch Pkwy.,

College Park, MD 20740,

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 9, 2009 (74 FR 33030), we issued a final rule requiring shell egg producers to implement measures to prevent Salmonella Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the final rule and to register with FDA. This final rule became effective September 8, 2009. In the Federal Register of July 13, 2011 (76 FR 41157), we made available a draft guidance entitled "Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation" and gave interested parties an opportunity to submit comments by September 12, 2011. We have reviewed and evaluated these comments and have modified the guidance where appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on how to interpret the requirements in the final rule, including questions and answers on compliance dates; coverage; definitions; SE prevention measures; sampling and testing for SE; registration; and compliance and enforcement. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910-0660.

III. Comments

Interested persons may submit written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Always access an FDA

document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: August 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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